

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,
BIOCON BIOLOGICS INC.,

Defendants.

Case No. 1:22-cv-00061-TSK

**REGENERON’S MOTION TO EXCLUDE
UNDISCLOSED EXPERT OPINION**

The Court made clear that there should not be “any sabotages or surprises” at trial, Pre-Trial Conf. at 72:19-20, yet Mylan and Biocon launched one on just the second day. Mere hours before Defendants’ first witness is set to take the stand, they revealed that he will offer an opinion not disclosed in his opening or reply report, or in Defendants’ invalidity contentions or pretrial memorandum. Abandoning all four theories Defendants previously advanced for why Regeneron’s ’865 product patent is purportedly invalid for obviousness, Defendants’ expert Barrett Rabinow will advance a new, fifth theory: that a person of ordinary skill in the art would combine Fraser, Liu, Dix, and Lucentis references (Gaudreault and Shams). This theory presumably comes with – as required by the Federal Circuit – new reasons why the POSA would be motivated to combine this particular set of references, and have a reasonable expectation of success in doing so. The Court should bar Dr. Rabinow from offering this newly advanced argument, disclosed far too late.

This issue should be resolved now, rather than after trial, because Defendants’ changed course directly affects the parties’ trial presentation. Regeneron built its case, including selecting

which claims to bring to trial, in reliance on Defendants’ *disclosed* arguments. If Dr. Rabinow is permitted to offer new opinions, Regeneron will be forced to cross-examine him on the fly, without having deposed him or even had a reasonable amount of time to consider the new theory. Then in its rebuttal case, Regeneron’s own expert will need to respond to Dr. Rabinow – again without an appropriate opportunity to analyze the new obviousness combination. Defendants should not be allowed to change the landscape now.

A. Background

In their invalidity contentions – disclosed six months ago – Defendants laid out four theories for how a POSA would have combined separate references to arrive at the invention of the ’865 patent, invalidating it as obvious. *First*, Defendants cited Fraser alone or in combination with one or more of Dix, Holash, and Liu. *See* Def. Final Inval. Conts. at 162. These references address cancer, pituitary-ovarian function, and immunological disorders.¹ *Second*, Defendants cited Wulff alone or in combination with Liu. *See id.* at 164. Wulff, like Fraser, concerns ovarian function.² *Third*, Defendants cited Dix alone or in combination with Liu. *See id.* at 165. Dix concerns cancer.³ *Fourth*, and finally, Defendants cited “one or more references describing the Lucentis formulation, in combination with one or more references disclosing aflibercept or VEGF Trap-Eye.” *Id.* at 166. Lucentis, of course, is a treatment for eye disorders. Defendants offered five examples of references disclosing aflibercept or VEGF Trap-Eye: the ’747 patent, Holash, Rudge, Vitti, Papadopoulos. *See id.* Most of these sources, like Lucentis, concern eye

¹ *See* DTX 0729.0001 (Fraser) (pituitary-ovarian function); DTX 2748.0002 (Dix) (cancer); DTX 3549.0001 (Holash) (cancer); DTX 3558.0030 (Liu) (immunological disorders).

² *See* DTX 3628.0002 (Wulff) (ovarian function).

³ *See* DTX 0013.0004 (’226 patent) (cancer).

disorders.⁴ Three – Holash, Rudge, and Papadopoulos – concern cancer.⁵ Holash addresses the structure of VEGF Trap; Papadopoulos similarly addresses the structure of several VEGF Traps and their properties. Rudge is a review article discussing the uses of VEGF Trap. The prior art combinations a challenger advances frame the obviousness case: they are the subject of fact discovery and then the focus of the parties’ expert reports and depositions.

Dr. Rabinow disclosed his initial expert report on February 2, 2023. He discussed forty-six references in the background of his report and then, *out of the millions of possible combinations of those references, he disclosed four specific combinations he asserted against Regeneron’s claims*. Those four combinations were a variation on the four combinations in Defendants’ contentions. Dr. Rabinow’s report was clear about the four combinations he asserted: “(1) Fraser (which incorporates Holash by reference), either alone or in combination with Dix and/or Liu and/or Andya ’801 (or Andya ’326); (2) Wulff, either alone or in combination with Dix and/or Liu and/or Andya ’801 (or Andya ’326); (3) the ’226 patent (or Dix), either alone or in combination with Liu and/or Andya ’801 (or Andya ’326); and (4) the prior art LUCENTIS (ranibizumab) formulations (as evidenced by Shams or Gaudreault), in combination with Fraser and/or the ’747 patent.” PTX-0055 ¶ 290.⁶

Dr. Rabinow’s reply report, disclosed on March 30, 2023, repeated the same combinations set forth in his initial report. *See* Rabinow Reply Rep. ¶¶ 90, 112, 119, 121.

⁴ DTX 2771.0001 (’747 patent) (“eye disorders” (abstract)); DTX 3592.0001 (Rudge) (“cancer and eye diseases”); DTX 3615.0001 (Vitti) (“eye diseases” (title)); DTX 3619.0036-.0037 (Papadopoulos) (assorted conditions including “eye disorders”).

⁵ DTX 3549.0001 (Holash) (“cancer”); DTX 3592.0001 (Rudge) (“cancer and eye diseases”); DTX 3619.0036-.0037 (Papadopoulos) (assorted conditions including “associated with tumors”).

⁶ Regeneron does not concede that the references are prior art or available for obviousness.

Defendants' pretrial memorandum, filed May 26, 2023, largely *narrowed* their asserted obviousness combinations. Now Defendants cited just three combinations: (1) Fraser with Dix and/or Liu and/or Andya '801, (2) Dix with Liu and/or Andya '801, and (3) Lucentis with Fraser and/or the '747 patent. *See* Dkt. 494-10. Once again, none of these combinations included both a cancer-treatment formulation and the treatment of eye disorders.

Finally, at 6:29 p.m. on Tuesday, June 14, 2023, Defendants disclosed the demonstrative slides they intend to use with their first trial witness, Dr. Rabinow. Those slides did not present any of the obviousness combinations described above. Instead, they offered a new one: Fraser, Dix, Lucentis (Shams and Gaudreault), and Liu. *See* DDX-1.77 – DDX-1.109. Never before had Defendants offered this combination of references.)

B. The Court Should Bar Defendants From Offering Their Late-Disclosed Expert Opinion

Expert witness disclosures must “be accompanied by a written report” containing “a complete statement of all opinions the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2)(B). In other words, “the expert report should . . . reflect[] the testimony the expert witness is expected to give at trial.” *Campbell v. United States*, 470 F. App'x 153, 156 (4th Cir. 2012).⁷ Defendants' disclosure — after trial began — of new combinations Dr. Rabinow contends render the '865 patent obvious violated their obligations under Rule 26, in exactly the manner the Court said at the pre-trial hearing in this matter that the parties should not do. As a result, Defendants are “not allowed to use” those opinions unless their “failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1). It was neither.

⁷ Because “[w]hether proffered evidence should be admitted in a trial is a procedural issue not unique to patent law,” the Fourth Circuit's interpretation of admissibility rules governs. *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1390-91 (Fed. Cir. 2003).

In the Fourth Circuit, courts “should be guided by” five factors in determining whether a nondisclosure was substantially justified or harmless. *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 596-97 (4th Cir. 2003). The so-called *Southern States* factors are:

(1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the non-disclosing party’s explanation for its failure to disclose the evidence.

Id. (quotation marks omitted). Defendants bear the burden of establishing harmlessness or justification. *Wilkins v. Montgomery*, 751 F.3d 214, 222 (4th Cir. 2014). Although a district court is “not *required* to tick through” each of the factors, *id.*, all of the *Southern State* factors weigh against Defendants.

First, if the Court allowed Dr. Rabinow to testify about these “undisclosed opinions at trial, they would be a surprise” to Regeneron. *Markle v. United States*, 2015 WL 4477726, at *3 (N.D.W. Va. July 22, 2015). *Second* and *third*, there is no opportunity to cure the surprise given that trial has already started. Courts routinely find that it “would be too late to cure the surprise,” and that doing so would disturb the trial, when parties disclose expert opinions after the close of discovery. *Id.*; *see also First Am. Title Ins. Co. v. Bowles Rice, LLP*, 2018 WL 316033, at *6 (N.D.W. Va. Jan. 5, 2018). These courts are worried that giving the other party its opportunity to respond would risk “disruption of the trial date and the [p]re-[t]rial scheduling order.” *Wilkins*, 751 F.3d at 222; *see also Whiting v. Butch*, 2016 WL 233690, at *3 (S.D.W. Va. Jan. 19, 2016). Disclosing a new obviousness theory after trial began is, of course, even more prejudicial to Regeneron, which had no opportunity to depose Dr. Rabinow concerning this combination. And obviousness is not just a matter of compiling a list of prior art. “A showing of obviousness requires a motivation or suggestion to combine or modify prior art references, coupled with a reasonable expectation of success.” *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough*

Corp., 320 F.3d 1339, 1354 (Fed. Cir. 2003). Defendants will need to support their new combination with new motivation and expectation theories, which are still mysteries to Regeneron.

Fourth, if the combination of Fraser, Dix, Lucentis, and Liu is important to Defendants, it should have disclosed it on time. *Southern States*, 318 F.3d at 598-99; *Cahoon v. Edward Orton, Jr. Ceramic Found.*, 2020 WL 918753, at *4 (E.D.N.C. Feb. 24, 2020) (excluding untimely expert medical reports “necessary” in an asbestos case because “the court would have expected much more diligence concerning expert disclosures”). *Finally*, Defendants can have no “explanation for its failure to disclose” Dr. Rabinow’s opinion until just before he testifies, favoring exclusion. *Southern States*, 318 F.3d at 597. That Dr. Rabinow’s deposition testimony foreclosed his previously disclosed theories does not, of course, justify substituting a new theory at trial.

The Federal Circuit has upheld the exclusion of expert opinions for simply “list[ing] a number of prior art references” without identifying which particular references to combine or why. *Innogenetics, N.V. v. Abbott Lab’ys*, 512 F.3d 1363, 1373 (Fed. Cir. 2008); *see also ActiveVideo Networks, Inc. v. Verizon Commc’ns, Inc.*, 694 F.3d 1312, 1327-28 (Fed. Cir. 2012) (deeming obviousness opinion insufficient where expert “failed to explain how specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, or how any specific combination would operate or read on the asserted claims”). Here, Dr. Rabinow’s reports disclosed specific combinations of prior art references as required. But Defendants’ attempt now to pick and choose from all of the prior art references identified and assert a new combination renders Dr. Rabinow’s report merely a list of prior art references, which should be excluded as in *Innogenetics*.

Courts throughout the nation routinely limit patent challengers to the specific prior art combinations disclosed in their invalidity contentions. For example, another court in this circuit excluded an expert opinion asserting “previously undisclosed combinations of those same prior art references,” enforcing rules requiring the defendants to identify expressly “any combinations of prior art showing obviousness.” *Changzhou Kaidi Elec. Co. v. Okin Am., Inc.*, 112 F. Supp. 3d 330, 334 (D. Md. 2015). Indeed, The Federal Circuit Bar Association model patent local rules make the same point, requiring “an identification of any combinations of prior art showing obviousness” early in the litigation. Rule 3-3(b), available at <https://fedcirbar.org/Portals/0/FCBA%20Model%20Patent%20Local%20Rules%20-%2020220311.pdf> (last visited June 14, 2023). To hold otherwise would allow a “shifting sands” approach to patent litigation. Similarly, the Eastern District of Texas, amongst the districts that adjudicates the most more patent disputes, requires “disclosure of combinations not just references” and has struck new obviousness combinations from an expert’s report disclosed three months before trial, finding that responding to new combinations is “a significant unexpected burden.” *LML Patent Corp.*, 2011 WL 5158285, at *1, *7 (E.D. Tex. Aug. 11, 2011). *See also BreathableBaby, LLC v. Crown Crafts, Inc.*, 2014 WL 3928526, at *4 (D. Minn. Aug. 12, 2014) (excluding attempt to add “new prior art combinations”). The rationale for exclusion is even stronger here. Defendants served Regeneron with its invalidity contentions in January 2023, *see* Dkt. 245. Dr. Rabinow disclosed his expert opinions in February 2023, *see* Dkt. 284. Dr. Rabinow was deposed in March 2023, *see* Dkt. 370. But it was only on the eve of his testimony that he disclosed a new combination of prior art references on which he apparently intends to rely.

CONCLUSION

The Court should preclude Defendants from offering an expert opinion about the non-obviousness of the '865 patent based on previously undisclosed combinations, including Fraser, Dix, Lucentis, and Liu.

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2023, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

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